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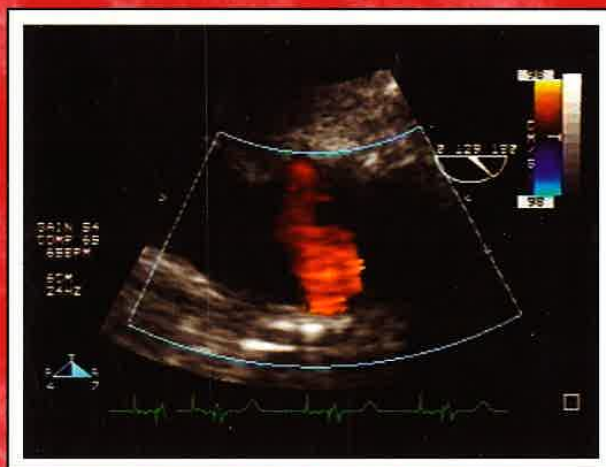
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CARDENE® I.V. (nicardipine hydrochloride)

Brief Summary of Prescribing Information

INDICATION AND USAGE: For the short-term treatment of hypertension when oral therapy is not feasible or desirable. For prolonged control of blood pressure, patients should be transferred to oral medication as soon as their clinical condition permits.

CONTRAINDICATIONS: In patients with known hypersensitivity. Cardene® I.V. is also contraindicated in patients with advanced aortic stenosis because part of the effect of Cardene® I.V. is secondary to reduced afterload. Reduction of diastolic pressure in these patients may worsen rather than improve myocardial oxygen balance.

WARNINGS: BETA-BLOCKER WITHDRAWAL: Nicardipine is not a beta-blocker and provides no protection against the dangers of abrupt beta-blocker withdrawal; any such withdrawal should be by gradual reduction of dose of beta-blocker.

RAPID DECREASES IN BLOOD PRESSURE: No clinical events have been reported suggestive of a too rapid decrease in blood pressure with Cardene® I.V. However, as with any antihypertensive agent, blood pressure lowering should be accomplished over as long a time as is compatible with patient's clinical status.

USE IN PATIENTS WITH ANGINA: Induction or exacerbation of angina has been seen in less than 1% of coronary artery disease patients treated with Cardene® I.V. Increased frequency, duration, or severity of angina has been seen with chronic oral Cardene® therapy.

USE IN PATIENTS WITH CONGESTIVE HEART FAILURE: Cardene® I.V. reduced afterload without impairing myocardial contractility in preliminary hemodynamic studies of CHF patients. However, *in vitro* and in some patients, a negative inotropic effect has been observed. Exercise caution when using Cardene® I.V., particularly in combination with a beta-blocker, in patients with CHF or significant left ventricular dysfunction.

USE IN PATIENTS WITH PHEOCHROMOCYTOMA: Limited clinical experience exists in these patients; therefore, exercise caution when administering Cardene® I.V.

PERIPHERAL VEIN INFUSION SITE: To minimize the risk of peripheral venous irritation, it is recommended that the site of infusion of Cardene® I.V. be changed every 12 hours.

PRECAUTIONS: GENERAL: Blood pressure: Because Cardene® I.V. decreases peripheral resistance, monitoring of blood pressure during administration is required. Cardene® I.V., like other calcium channel blockers, may occasionally produce symptomatic hypotension. Caution is advised to avoid systemic hypotension when administering the drug to patients who have sustained an acute cerebral infarction or hemorrhage.

Use in Patients with Impaired Hepatic Function: Nicardipine is metabolized in the liver; exercise caution in patients with impaired liver function or reduced hepatic blood flow; consider use of lower dosages. Nicardipine administered intravenously has been reported to increase hepatic venous pressure gradient by 4 mm Hg in cirrhotic patients at high doses (5 mg/20 min). Use Cardene® I.V. with caution in patients with portal hypertension.

Use in Patients with Impaired Renal Function: When Cardene® I.V. was given to mild to moderate hypertensive patients with moderate renal impairment, a significantly lower systemic clearance and higher AUC was observed. These results are consistent with those seen after oral administration of nicardipine. Careful dose titration is advised when treating renally-impaired patients.

DRUG INTERACTIONS: Since Cardene® I.V. may be administered to patients already being treated with other medications, including other antihypertensive agents, careful monitoring of these patients is necessary to detect and promptly treat any undesired effects from concomitant administration. Beta-blockers: In most patients Cardene® I.V. can safely be used with beta-blockers. However, exercise caution when using this combination in CHF patients (see WARNINGS).

Cimetidine: Cimetidine has been shown to increase nicardipine plasma concentrations following Cardene® capsule administration; carefully monitor concomitant use. Data with other histamine-2 antagonists are not available.

Digoxin: Studies have shown that Cardene® capsules usually do not alter digoxin plasma concentrations; however, as a precaution, evaluate digoxin levels when initiating concomitant Cardene® I.V. therapy.

Fentanyl anesthesia: Hypotension has been reported during fentanyl anesthesia with concomitant use of a beta-blocker and a calcium channel blocker. Even though such interactions were not seen during clinical studies with Cardene® I.V. (nicardipine hydrochloride), an increased volume of circulating fluids might be required if such an interaction were to occur.

Cyclosporine: Concomitant use of Cardene® capsules and cyclosporine results in elevated plasma cyclosporine levels. Monitor cyclosporine plasma levels closely and reduce its dose accordingly. *In vitro* interaction: The plasma protein binding of nicardipine was not altered when therapeutic concentrations of furosemide, propranolol, dipyridamide, warfarin, quinidine, or naproxen were added to human plasma *in vitro*.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Rats treated with nicardipine in the diet (at doses of 5, 15, or 45 mg/kg/day) for two years showed a dose-dependent increase in thyroid hyperplasia and neoplasia (follicular adenoma/carcinoma). One- and three-month rat studies have suggested that these results are due to a nicardipine-induced reduction in plasma thyroxine (T₄) levels, with resultant increase in plasma levels of thyroid stimulating hormone (TSH). Mice treated with nicardipine in the diet (at concentrations calculated to provide daily dosage levels of up to 100 mg/kg/day) for up to 18 months showed no evidence of neoplasia of any tissue and no evidence of thyroid changes. There was no evidence of nicardipine-induced thyroid effects in dogs (treated with nicardipine at doses up to 25 mg/kg/day for one year) or in man. Nicardipine did not display mutagenic potential in genotoxicity tests conducted in microbes, mice and hamsters. No fertility impairment was seen in male or female rats administered oral nicardipine doses as high as 100 mg/kg/day (50 times the 40 mg TID maximum recommended human dose [MRHD] in man, assuming a patient weight of 60 kg).

PREGNANCY CATEGORY C: There are no adequate and well-controlled studies in pregnant women; Cardene® I.V. should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Cardene® I.V. administered at doses up to 5 mg/kg/day and up to 0.5 mg/kg/day to pregnant rats and rabbits, respectively, produced no embryotoxicity or teratogenicity. Embryotoxicity, but not teratogenicity, was seen at 10 mg/kg/day in rats and at 1 mg/kg/day in rabbits. Nicardipine was embryocidal at oral doses of 150 mg/kg/day, given during organogenesis, to pregnant white rabbits but not at 50 mg/kg/day (25 times MRHD). No adverse effects on the fetus were observed when albino rabbits were treated, during organogenesis, with up to 100 mg/kg/day of nicardipine. Pregnant rats receiving oral doses up to 100 mg/kg/day (50 times MRHD) showed no evidence of embryolethality or teratogenicity. However, dystocia and reductions in birth weights, neonatal survival, and neonatal weight gain were noted. There are no adequate and well-controlled studies in pregnant women. Cardene® should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS: Studies in rats have shown significant concentrations of nicardipine in maternal milk. Therefore, use in nursing mothers is not recommended.

PEDIATRIC USE: Safety and efficacy in patients under the age of 18 have not been established.

USE IN THE ELDERLY: In clinical studies, no significant difference was observed in the antihypertensive effect of Cardene® I.V. in patients ≥65 years compared to other adult patients.

ADVERSE EXPERIENCES: 244 patients participated in two multicenter double-blind, placebo-controlled trials of Cardene® I.V. Adverse effects were generally not serious and most were expected effects of vasodilation. Some adverse effects required dosage adjustments. Therapy was discontinued in approx. 12% of patients due mainly to hypotension, headache and tachycardia.

The following numbers represent percentages of patients with adverse experiences during the double-blind portion of controlled trials with Cardene® I.V. (n=144) versus Placebo (n=100), respectively.

Percent of Patients with Adverse Experiences
During the Double-Blind Portion of Controlled Trials

Adverse Experience	Cardene (n=144)	Placebo (n=100)
Body as a Whole		
Headache	14.6	2.0
Asthenia	0.7	0.0
Abdominal pain	0.7	0.0
Chest pain	0.7	0.0
Cardiovascular		
Hypotension	5.6	1.0
Tachycardia	3.5	0.0
ECG abnormality	1.4	0.0
Postural hypotension	1.4	0.0
Ventricular extrasystoles	1.4	0.0
Extrasystoles	0.7	0.0
Hemopericardium	0.7	0.0
Hypertension	0.7	0.0
Supraventricular tachycardia	0.7	0.0
Syncope	0.7	0.0
Vasodilation	0.7	0.0
Ventricular tachycardia	0.7	0.0
Digestive		
Nausea/vomiting	4.9	1.0
Injection Site		
Injection site reaction	1.4	0.0
Injection site pain	0.7	0.0
Metabolic and Nutritional		
Hypokalemia	0.7	0.0
Nervous		
Dizziness	1.4	0.0
Hypesthesia	0.7	0.0
Intracranial hemorrhage	0.7	0.0
Paresthesia	0.7	0.0
Respiratory		
Dyspnea	0.7	0.0
Skin and Appendages		
Sweating	1.4	0.0
Urogenital		
Polyuria	1.4	0.0
Hematuria	0.7	0.0

RARE EVENTS: The following events have been reported in clinical trials or in the literature with intravenous use of nicardipine. *Body as a Whole:* fever, neck pain. *Cardiovascular:* angina pectoris, atrioventricular block, ST segment depression, inverted T wave, deep vein thrombophlebitis. *Digestive:* dyspepsia. *Hemic and Lymphatic:* thrombocytopenia. *Metabolic and Nutritional:* hypophosphatemia, peripheral edema. *Nervous:* confusion, hypertonia. *Respiratory:* respiratory disorder. *Special Senses:* conjunctivitis, ear disorder, tinnitus. *Urogenital:* urinary frequency. Sinus node dysfunction and myocardial infarction, possibly due to disease progression, have been seen in patients on chronic oral nicardipine therapy.

OVERDOSAGE: Several overdosages with orally administered nicardipine have been reported. One adult patient allegedly ingested 600 mg of nicardipine (standard immediate release) capsules, and another patient, 2160 mg of the sustained release formulation of nicardipine. Symptoms included marked hypotension, bradycardia, palpitations, flushing, drowsiness, confusion and slurred speech. All symptoms resolved without sequelae. An overdosage occurred in a one year old child who ingested half of the powder in a 30 mg nicardipine standard capsule. The child remained asymptomatic. Based on results obtained in laboratory animals, lethal overdoses may cause systemic hypotension, bradycardia (following initial tachycardia) and progressive atrioventricular conduction block. Reversible hepatic function abnormalities and sporadic focal hepatic necrosis were noted in some animal species receiving very large doses of nicardipine.

For treatment of overdosage, standard measures including monitoring of cardiac and respiratory functions should be implemented. The patient should be positioned so as to avoid cerebral anoxia. Frequent blood pressure determinations are essential. Vasopressors are clinically indicated for patients exhibiting profound hypotension. Intravenous calcium gluconate may help reverse the effects of calcium entry blockade.

DOSAGE AND ADMINISTRATION: DOSAGE MUST BE INDIVIDUALIZED depending on severity of hypertension and patient response. Monitor blood pressure during and after the infusion; avoid too rapid or excessive reductions in systolic or diastolic blood pressure.

WARNING: AMPULS MUST BE DILUTED BEFORE INFUSION.

Cardene® I.V. is administered by slow continuous intravenous infusion at a CONCENTRATION OF 0.1 mg/mL. Dilute each ampul (25 mg) with 240 mL of compatible intravenous fluid (see full prescribing information), resulting in 250 mL of a 0.1 mg/mL solution. **NOTE: Cardene® I.V. is NOT compatible with Sodium Bicarbonate (5%) Injection, USP, or Lactated Ringer's Injection, USP.**

See package insert for full prescribing information.

Reference:

1. Whiting RL. Animal pharmacology of nicardipine and its clinical relevance. *Am J Cardiol.* 1987;59:3J-8J.

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Selective Left Bronchial Intubation and Left-Lung Isolation in Infants and Toddlers: Analysis of a New Technique

Suresh Chengod, MD, Aluvangal Pulparambil Chandrasekharan, MS, MCh, FRCS, and Padmanabhan Manoj, MS, MCh

Objectives: The purpose of this study was to analyze and compare a new technique for left bronchial intubation and left-lung isolation in infants and toddlers without the help of bronchoscopes.

Methods: In this prospective, unique comparative study, 3 different techniques for left mainstem bronchus intubation and left-lung isolation using a Fogarty catheter as a bronchial blocker were conducted in 11 children under age 4 who required left-lung isolation for left-lung surgery. A new technique for Fogarty catheter insertion and balloon inflation for proper positioning and avoiding displacement during lung handling was used. The first technique was a blind introduction to the left bronchus of the endotracheal tube (ETT) with the head turned to the right and the tube turned to the left at 180°. The second one was to introduce the preshaped Fogarty catheter to the left bronchus. The third one was to intubate the left bronchus using the new technique of a preshaped ETT.

INFANTS AND TODDLERS may benefit if lung isolation is achieved for surgical management of suppurative lung diseases and bleeding from the lungs. Experience with one-lung ventilation (OLV) in infants and toddlers has been very limited when compared with older children and adults. The reason may be the unavailability of double-lumen endotracheal tubes for this age group until the mid-1990s¹⁴ and even after that their limited availability for clinical use.¹²

The need to have small-size fiberoptic bronchoscopes (FOBs) or rigid bronchoscopes for proper placement of endobronchial blockers in this age group and limited experience of anesthesiologists with these instruments also contribute to the difficulties of performing thoracotomies in the prone position.¹

Vale² and Cay et al³ have described the use of Fogarty catheters as endobronchial blockers in children. Recently, wire-guided endobronchial blockers¹³ and various other bronchial blockers,^{12,15} some of them used coaxially through the single-lumen endotracheal tube^{12,16} (SLET), have been described for lung isolation in children. Endobronchial intubation as a technique for lung isolation has been mentioned⁴ and practiced in units doing thoracotomies in these patients. Right endobronchial intubation with an SLET, specifically with a cuffed tube, for left-lung surgery results in right upper-lobe bronchus obstruction and will lead to severe hypercarbia and hypoxia. On the other hand, right-lung surgery can be performed with left mainstem bronchial intubation with or without right bronchial

Results: No left bronchial intubation could be achieved with the first technique. Left bronchial intubation and isolation were achieved in 2 of 11 by the second technique and 10 of 11 using the third technique. No bulb displacement occurred in any of these during lung handling.

Conclusion: The new technique of left bronchial intubation with a preshaped endotracheal tube was simple, safe, and easily accomplished. A Fogarty catheter can be positioned properly without the aid of a smaller bronchoscope once the left bronchus is intubated. Balloon displacement can be avoided completely if the left lung is collapsed properly and completely before the final balloon inflation. © 2005 Elsevier Inc. All rights reserved.

KEY WORDS: left bronchial intubation, lung isolation, lung surgery, bronchial blocker, Fogarty catheter, infants

blockade. Availability of a flexible FOB that can easily pass even through an SLET of 3-mm internal diameter is essential for the accurate placement of either the bronchial blocker or the endobronchial tube in the small left bronchus of children in this age group.

The purpose of this investigation was to compare 2 described techniques and compare them with a new technique for the case of left bronchial intubation and left-lung isolation with the appropriate-size Fogarty catheter, without the help of bronchoscopes. Two of these techniques are already mentioned in the literature^{5,6} and the authors developed the third, a new technique. The authors also analyzed a technique for accurate inflation and proper positioning of a Fogarty catheter balloon without causing dislodgement during lung handling by the surgical team.

METHODS

After ethics committee approval of the protocol and informed consent from the parents, this prospective study was conducted over a period of 3 years. Eleven children under the age of 4 were studied. There were 9 boys and 2 girls with a median age of 1.6 years (range 0.6-3.5 years), median weight of 9.1 kg (range 6.2-12.5 kg), and median height of 78 cm (range 58-100 cm).

The infrequent presentation of infants with an isolated left-lung pathology requiring left thoracotomy and lung resection forced the authors to formulate and use a unique way of comparing 3 different techniques for left bronchial intubation and left bronchus blockade with a Fogarty catheter. The specifications were as follows:

1. Children under 4 years requiring surgical treatment for either suppurative lung disease or bleeding from the lungs, involving the left lung, in whom left thoracotomy and left-lung resection were planned were included in the study.
2. All children had all 3 techniques studied on them.
3. The drawing lot decided the sequence of techniques in each patient.
4. The same anesthesiologist tried the 3 techniques in all patients to avoid subjective changes in techniques and expertise.
5. Only a single attempt was made for each technique in a patient.

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6. Confirmation and documentation of the Fogarty position was done using a 2.5-mm FOB (Karl Storz) after each successful attempt.
7. Final lung isolation before proceeding with the surgery was done with the new technique, which is being tested. Fiberoptic aid was always at hand if this technique failed.

On arrival in the operating room, routine noninvasive monitors were connected. Anesthesia was induced with 5% to 8% sevoflurane in 100% oxygen. Intravenous access was secured and patency maintained with a slow infusion of crystalloid intravenous fluid. After 10 $\mu\text{g/kg}$ of fentanyl and glycopyrrolate, vecuronium, 0.2 mg/kg, was used to aid intubation of the trachea with the proper sized noncuffed SLET (SIMS Portex Ltd, Hythe, Kent, UK). Anesthesia was maintained during the lung isolation procedure with propofol, 5 mg/kg/h, and fentanyl, 0.03 $\mu\text{g/kg/min}$, as continuous infusion. An intra-arterial catheter was secured, and invasive arterial blood pressure was monitored. A double-lumen central venous catheter was placed in the right internal jugular vein and central venous pressure was monitored. End-tidal carbon dioxide, fraction of inspired oxygen, and anesthetic gas concentration were measured and monitored by a side-stream gas analyzer.

First, the carinal distance was measured from the central upper incisor or the gum of the upper jaw. The SLET already in the trachea was slowly advanced down the trachea, 0.5 cm at a time, while listening to the breath sounds on each hemithorax with each advancement until air entry was absent or there were diminished breath sounds in one lung and at the same time normal breath sounds in the other lung. This distance from the previously described reference point was noted and marked on the SLET and was considered as the carinal distance. The SLET was then pulled into the midtrachea and ventilation continued.

The measured carinal distance was then marked on another SLET 1 size smaller than the one in the patient, measuring from the tip of the tube. Two more markings were made on this tube, one at 0.5 cm and another 1 cm proximal to the mark of carinal distance (Fig 1). A Fogarty catheter was selected, as a bronchial blocker, according to the age of the patient; 4F catheter in the group less than 1 year, 5F in 1 year to 2 years old group, and 6F in the group between 2 years and 4 years. Three markings were made on the Fogarty catheter to aid accurate placement in the left mainstem bronchus. The first mark made on the catheter was the carinal distance as measured from the tip of the catheter. The second mark was the carinal distance measured from the proximal joint of the balloon and the third mark was made 1 cm proximal to the second mark (Fig 1). Techniques that were compared with each other for the ease of left mainstem bronchial intubation followed by bronchial blocker placement and finally left-lung isolation are described.

Technique 1: Normal Endotracheal Tube Technique

An SLET, which is 1 size smaller than the appropriate size tube and on which the measured carinal distance is marked, was introduced into the midtrachea by direct laryngoscopy. The head and the SLET were held in the normal intubating position. The patient's head was then turned to the right as much as possible and then the SLET turned by 180°. The tube was then advanced to enter the bronchus up to the third mark (ie, 1 cm more than the carinal distance). Proper placement of the endotracheal tube tip in the left mainstem bronchus was then confirmed by auscultation of the chest over both lungs. Air entry only to the left with absent or significantly diminished breath sounds over the right chest confirmed proper left mainstem bronchial intubation. Once left mainstem bronchial intubation was successfully achieved, in a single attempt, Fogarty isolation was then performed as described below. The technique of Fogarty positioning was the same for all 3 techniques studied.

A Fogarty catheter of appropriate size without the stylet and with the markings made on it, as described earlier, was then passed through the

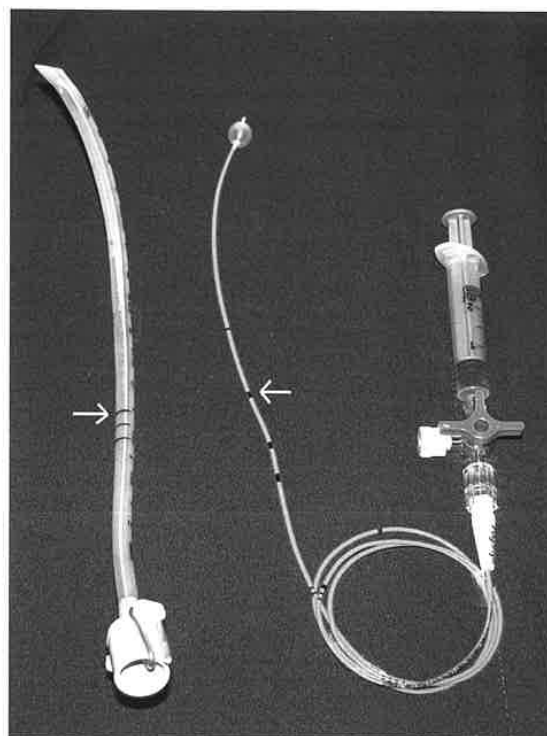


Fig 1. Endotracheal tube modified to resemble a left-sided double-lumen tube with the help of a stylet. Note the bevel of the tube facing toward the right side. Carinal distance is marked on the tube and the catheter as measured from the tip (Arrows). The second and third markings on the catheter, from below upwards, are the carinal distance from the proximal joint of the balloon and 1 cm from the second mark, respectively.

SLET already positioned in the left mainstem bronchus (now the endobronchial tube). The Fogarty catheter was advanced as far down as possible until it met with resistance. The endobronchial tube was then removed over the Fogarty catheter from the trachea, stabilizing the catheter in position. The trachea of the patient was then intubated with another SLET, alongside the Fogarty catheter, the size of which was the same as the endobronchial tube used earlier. This tube was then positioned in the midtrachea and secured with tapes. The Fogarty catheter was then pulled out so that the most proximal mark made on the catheter (the first mark seen while pulling out) came to the level of the incisor or the gum of the upper jaw. The SLET should now be in the midtrachea and the Fogarty catheter in the left mainstem bronchus with the proximal joint of the balloon 1 cm beyond the carina into the left mainstem bronchus. The Fogarty catheter was then securely taped to the SLET. The Fogarty catheter balloon was then filled slowly with air using a 1-mL or 2-mL syringe (according to the size of the Fogarty selected) mounted on a 3-way stopcock attached to the hub of the catheter. The left lung field was auscultated while ventilating both lungs through the SLET, and the volume of air injected into the balloon, when there was no air entry to the left lung, was noted. This was considered to be the amount of air to be injected into the balloon to get an airtight fit during the final isolation. The time taken from the point of initiation of endobronchial tube intubation to the point of lung isolation was noted.

Technique 2: Preshaped Fogarty Catheter Technique

Blind introduction of the Fogarty catheter into the left bronchus was tried in this technique without the aid of bronchoscopes or prior selective intubation of the left bronchus as described in the previous technique. An appropriately sized Fogarty catheter, with the stylet in situ, was bent just proximal to the balloon to about 30°. This Fogarty catheter was then introduced into the trachea by normal direct laryngoscopy with the bent tip turned to the left. The Fogarty catheter was advanced as far down as possible into the bronchus and the stylet removed. The trachea was then intubated with an SLET 1 size smaller than what was appropriate for the child and the tip positioned in the midtrachea. After fixing the SLET, the Fogarty catheter was withdrawn until the third mark from the tip (the first mark seen while pulling out) was at the incisor level of the upper jaw. The catheter balloon was then inflated and on ventilation through the SLET, absence of air entry to the left confirmed accurate placement of the catheter in the left mainstem bronchus. Absent or diminished air entry in the right lung with normal air entry in the left lung suggests right bronchial placement of the Fogarty catheter and was considered as failure of the technique. If left lung isolation was achieved, then the time taken from the point of introduction of catheter into the trachea to the point of lung isolation was noted.

Technique 3: Preshaped Endotracheal Tube Technique

In this technique, the second endotracheal tube (endobronchial tube), which was 1 size smaller than the appropriate-sized tube, was preshaped to resemble the shape of a left-sided double-lumen disposable Robertshaw endobronchial tube and the actual technique was as described later. A malleable intubating stylet of size 6F or 8F (Satin-Slip, Mallinckrodt Inc, St. Louis, MO) was placed in the second SLET (1 size smaller) and fixed so that the tip of the stylet was immediately above the bevel of the tube. Molding the stylet retains the normal tube curvature with the anterior concavity. The SLET was then rotated over the stylet to 180° so that the bevel, which was facing to the left, now faced right and 15° to 20° bend to the left was made close to the tip of the endotracheal tube (Fig 1). (The stylet holds the tube in position with the tip turned to the left, bevel facing right and normal anterior concavity.) This preshaped tube was then introduced into the trachea and left bronchus, with the stylet in place, just like a left-sided double-lumen endobronchial tube intubation. This endobronchial tube was then passed into the bronchus so that the third mark on the tube corresponded to the incisor or the gum of the upper jaw. The stylet was then removed, stabilizing the tube in position. The lung was then ventilated and the proper position of the tube tip in the left mainstem bronchus was confirmed by the air entry only to or preferentially to the left lung.

Lung isolation using the Fogarty catheter was then performed as described under technique 1, once the correct placement of the endobronchial tube in the left bronchus was confirmed as mentioned earlier. Time taken from the point of intubation using the preformed tube to the point of lung isolation was noted. As mentioned in the protocol, for the final lung isolation and to proceed with the surgery, the third technique was used in all patients (if this technique was not the last one to be tested according to the lots drawn), but no inferences were made and had no bearing on the study as far as the success of left endobronchial intubation was concerned.

Once the bronchial blocker and SLET were secured in position for the surgery, anesthesia was maintained with isoflurane 1% (as set on the vaporizer), vecuronium, 3 µg/kg/min, and fentanyl, 0.03 µg/kg/min. Before positioning the patient in the right lateral decubitus position, both lungs were ventilated with an FiO_2 of 1, a tidal volume of 8 mL/kg, and a respiratory rate for a PaCO_2 of 35 to 40 mmHg. Mechanical ventilation was provided with a Datex Ohmeda 7100 ventilator (Aestiva 5; Datex Ohmeda Inc, Madison, WI). Arterial blood gas

estimations were done after 15 minutes of any change made in the ventilatory setting or it was repeated every 30 minutes when on OLV.

The final left-lung isolation before positioning the patient in the right lateral decubitus position was initiated as follows. The SLET was disconnected from the breathing circuit, and a continuous negative suction was applied using a vacuum suction catheter placed in the trachea close to the carina. A continuous circumferential gentle squeezing pressure was applied on the chest wall, with both hands of the clinician embracing the chest wall, well before inflating the Fogarty balloon, and continued until the balloon was inflated adequately with the previously assessed volume of air. OLV of the right lung was then initiated and the patient positioned in the right lateral decubitus position. The same surgical team performed all thoracotomies, and the adequacy of left-lung collapse was assessed by them on a 3-stage scale and graded as follows: total collapse and no ventilation (excellent), partial collapse but no ventilation (good), ventilation present (poor). Dislodgement of the catheter was suspected when the peak airway pressure suddenly increased with absent or decreased air entry on the right side of the chest with or without the ventilation of the left lung.

On completion of the procedure, adequate suction clearance of any secretions from the air way was done and the Fogarty balloon deflated. Ventilation of both lungs was resumed. Before shifting to the intensive care unit, the Fogarty catheter was removed and the trachea reintubated with the appropriate-sized SLET. The trachea and bronchi were examined with an FOB for any injury inflicted during the procedure. All patients received caudal epidural preservative-free buprenorphine in a dose of 5 µg/kg in 0.5 mL/kg (maximum of 10 mL) of normal saline for postoperative analgesia. All patients were ventilated in the intensive care unit until their body temperature became normal, the neuromuscular blocker effect reversed, and they were extubated. Rectal paracetamol was used to supplement postoperative analgesia, if required. All patients received 0.25 mg/kg of dexamethasone in the operating room itself and prophylactic racemic Epinephrine nebulization after extubation was used to prevent glottic edema and postoperative stridor. The authors compared the data by McNemar test and a p value of <0.05 was considered significant.

RESULTS

Left upper lobectomy ($n = 4$), left lower lobectomy ($n = 6$), and decortication ($n = 1$) were the surgeries performed. A summary of the important aspects of these cases is given in Table 1. Success of left bronchial intubation and isolation with 3 different techniques is summarized in Table 2. None of the 11 patients' left bronchus could be intubated with technique 1. Two of 11 was the success rate of left bronchial intubation and isolation using technique 2, and the time for isolation was 5 minutes and 7 minutes, respectively. Ten of eleven patients' left bronchus could be intubated and isolated by using technique 3. Comparisons between the success rates of technique 3 with the other 2 were statistically significant with a p value <0.05 . The mean time for isolation with technique 3 was 9.13 ± 0.11 minutes (range 7.29–11.23 minutes). Balloon occlusion volume ranged from 0.75 mL to 1.8 mL of air. The adequacy of separation by technique 3, which was later used to isolate the lung, was assessed as excellent in 6 patients and good in 4 patients. There were no incidences of Fogarty catheter balloon displacement in any of these 11 cases after lung handling during surgery.

In 1 patient in whom left bronchial intubation could not be achieved with any of the 3 techniques, it was done with the help of a 2.5-mm FOB and then Fogarty catheter isolation was done as described earlier. Table 3 shows the carinal distance mea-

Table 1. Patient Characteristics

Age (y)	Sex	Weight (kg)	Height (cm)	Diagnosis	Surgery
2.3	F	12	83	Sequestered lung	LLL
3.6	M	12.5	101	Empyema	Decortication
3.1	M	11	95	Destroyed lung	LUL
0.7	M	6.2	64	Infected lung cyst	LUL
1.8	F	9	78	Lung abscess-? FB	LLL
0.9	M	6.4	69	Lung abscess	LLL
1.4	M	8.6	72	Bronchiectasis—destroyed lung	LUL
0.6	M	6.9	59	Lung cyst	LUL
1.11	M	10.3	77	FB—destroyed lung	LLL
2.1	M	11.1	87	Bronchiectasis	LLL + lingulectomy
1.6	M	9.1	73	Lung abscess	LLL

Abbreviations: M, male; F, female; FB, foreign body; LLL, left lower lobectomy; LUL, left upper lobectomy.

sured, Fogarty catheter size selected, balloon volume used, and the time taken for isolation.

DISCUSSION

Isolation of the diseased lung and OLV are desirable in infants and toddlers undergoing surgical management for infected lungs, bleeding from the lungs, and sometimes even congenital lobar emphysema. Spillage of infected material and blood from the operated lung to the normal lungs might lead to increased postoperative morbidity and could even be life-threatening during the intraoperative period. In contrast to adults and bigger children, in whom double-lumen tubes and Univent tubes¹² are available for lung separation and OLV, lung isolation in infants and small children requires endobronchial tube placement⁴, a bronchial blocker,^{2-4,7,12-16} or both⁸ to achieve adequate isolation and OLV.

Right-sided thoracotomies and lung surgery can be performed by left bronchial intubation with or without a bronchial blocker in the right mainstem bronchus. Left-lung surgery carries a higher risk of hypoxia and severe hypercarbia when done with right bronchial intubation, especially with a cuffed SLET. This is mainly because of the invariable occlusion of the right upper lobe bronchus by the right-sided endobronchial tube, especially in infants. Even if the right-sided endobronchial tube is placed just proximal to the upper lobe bronchus takeoff, no safety is guaranteed against spillage because the right mainstem bronchus above the upper lobe takeoff is too short to hold the endobronchial tube and will invariably dislodge into the trachea during surgical manipulation, resulting in disastrous consequences, especially in smaller children.

The best option for left-sided lung surgeries in this age group would be to place a balloon-tipped bronchial blocker, usually a Fogarty catheter⁷ of appropriate size, or an end-hole balloon

wedge catheter^{12,16} or wire-guided endobronchial blocker (WEB),¹³ well into the left mainstem bronchus (which is longer than the right mainstem bronchus) and to ventilate the right lung with a well-fitting endotracheal tube placed in the midtrachea. Coaxially placed bronchial blockers through the SLET invariably require small-sized FOBs and multipoint adaptors, and different sizes of FOBs are required depending on the size of the SLET the patient's trachea will require.¹⁶ Simultaneous passage of the 5F end-hole bronchial blocker and FOB of even less than 2-mm outer diameter, for positioning the balloon of the bronchial blocker in the bronchus, through an SLET of size less than 4.5-mm internal diameter (ID) would be very difficult. Smaller Univent tubes are available in sizes as small as 3.5- and 4.5-mm ID for use in children over 6 years of age.¹²

The advantages of the Fogarty catheter are its easy availability in different sizes with varying balloon inflation volumes and relatively lower cost than other commercially available bronchial blockers. Its drawbacks are the low-volume high-pressure balloon and the absence of a central lumen for suctioning and oxygen insufflation, if required, and the increased chance of dislodgement of the blocker balloon into the trachea during lung manipulation. In infants and smaller children, left bronchial intubation for right-lung surgery or the placement of a bronchial blocker in the left mainstem bronchus require skill, availability, and proficiency in the usage of small FOBs or small rigid bronchoscopes. Small FOBs that can pass through endotracheal tubes of size 3.5 or less may not be readily available in many centers, and technical difficulty, lack of experience, and infrequent use of rigid bronchoscopes by the anesthesiologist in these small patients will lead to some compromise in lung separation in these patients. In this study, 2 previously described techniques for selective left bronchial intubation were compared with a newer technique.

Using the first technique described by Kubota et al⁵, the success rate was nil when compared with 92% success in their study involving 59 children. One reason for this low success rate could be that the number of patients in the present study group was less. In Kubota et al's study, they did not mention how many of these 59 children were below 4 years of age. Because the authors had other parameters to be analyzed throughout the study, only those children below 4 years of age who required a left thoracotomy could be included. Confirmation of proper tube placement in both studies was done by

Table 2. Success of Left Bronchial Intubation

Techniques	Normal ETT (TEC I)	Preformed Fogarty Catheter (TEC II)	Preformed ETT (TEC III)
Success Rate	0/11	2/11	10/11
% of success	0%	18.18%	90.9%

NOTE. Comparing TEC I with TEC III; p value < 0.05. Comparing TEC II with TEC III; p value < 0.05.

Abbreviation: ETT, endotracheal tube.

Table 3. Measured Parameters and Values

Age (y)	Carinal Distance (cm)	Fogarty Catheter		Time for Isolation (mins)		
		Size (F)	Balloon Volume (cc)	Tec I	Tec II	Tec III
0.6	12	4	0.75	NA	NA	8.12
0.7	12.5	4	0.75	NA	NA	9.36
0.9	13	4	0.75	NA	NA	8.25
1.4	14	4	1.1	NA	NA	10.11
1.6	13.5	5	1.3	NA	5	11.23
1.8	14	5	1.1	NA	NA	9.10
1.11	14	5	1.3	NA	NA	7.29
2.1	15.5	5	1.4	NA	7	9.18
2.3	15	5	1.4	NA	NA	8.44
3.1	16	5	1.5	NA	NA	NA
3.6	16.5	6	1.8	NA	NA	10.21

Abbreviation: NA, not applicable.

auscultation alone. The authors attempted intubation only once in each patient and that could be another reason for total failure. Kubota et al⁵ did not mention how many attempts were made in each patient even though they did mention the time for left bronchial intubation to be 4 to 5 seconds.

The second technique of left-lung isolation using the preshaped Fogarty catheter was described by Ginsberg.⁶ In his study, he used 8-to-14 size Fogarty catheters with the tip angled at 30°. He did not mention the success rate, but the Fogarty size does not seem to fit in the group that the authors studied. The authors' success rate was only 18.18% (ie, 2 of 11 patients). The authors confirmed left bronchial placement of the Fogarty catheter by auscultation alone but Ginsberg had used FOB for proper positioning. Thus, the authors' technique being totally blind and also in smaller children with a single attempt could be the reasons for this low success rate.

Using the third technique, developed by the authors' group, the success rate was 90.9% (ie, 10 of 11 patients). The side to which the tube bevel faces during intubation determines which bronchus the endobronchial tube would enter if it were advanced beyond the carina. Baraka et al⁹ documented this. The conclusion of Kubota et al¹⁰ that the angle of tracheobronchial relationship favored the preferential passage of the endotracheal tube to the right bronchus in children was challenged by Block,¹¹ who suggested that the bevel of the normal endotracheal tube that faces the left determined the tube's passage to the right bronchus when pushed beyond the carina. Baraka et al⁹ mentioned a 100% success rate of left bronchial intubation with the bevel facing right. In the present study this was modified by preshaping the tube with a stylet inside to resemble a left-sided double-lumen tube and the bevel to face to the right. In 1 patient who could not be intubated, the left bronchus had an abnormal angle of takeoff and a smaller bronchial lumen than the tube selected by the authors according to the protocol.

Once the left bronchus was intubated, the Fogarty catheter placement and proper positioning of the balloon were achieved in all patients. Even though the whole procedure was blind, confirmation of bronchial blocker placement with FOB showed absolutely accurate positioning of the balloon proximal to the left upper lobe bronchus takeoff.

Intubating the infant trachea with the preshaped SLET, keeping the stylet inside, has the inherent risk of injuring the trachea or bronchus. Lateral deviation of 15° to 20° close to the tip of the SLET, which is 1 size smaller than a tube that the trachea would have accommodated, does not produce so much deviation of the long axis of the SLET as to cause any undue pressure on the lateral wall of the trachea and thus injury to the tracheal mucosa. The authors were very careful with intubating this preshaped SLET so that the tube was never advanced farther into the trachea or bronchus at the slightest feel of resistance, which was encountered in only 1 case. The trachea and bronchi of all these patients were examined with FOB after the procedure, and no signs of tracheal or bronchial injury were found. None of them developed postoperative stridor.

Fiberoptic bronchoscopy is the accepted standard to aid and confirm the placement of double-lumen endotracheal tubes and bronchial blockers, even more essential in the placement of WEB or more recently described end-hole bronchial blockers¹⁶ and Univent tubes. In this study, the authors tried to prove that accurate placement of bronchial blockers can still be achieved, especially in smaller children, when smaller bronchoscopes are not available. Fogarty catheters are relatively thinner for a given balloon volume, when compared with other bronchial blockers, and thus will allow the use of endotracheal tubes of larger ID, especially in infants and smaller children when they are placed side by side in the trachea. The authors found that coaxial placement of bronchial blockers through indwelling SLET of size less than 4 mm ID leads to difficulty and compromise in airway suction clearance and inadvertent pulling and dislodgement of the blocker balloon during tracheal toilet.

The technique of collapsing the lung before the final Fogarty balloon inflation and positioning in the right lateral decubitus position prevented the balloon displacement during surgery and lung handling. This particular procedure can lead to a sudden reduction in functional residual capacity and thus acute hypoxemia. In the authors' limited experience, this problem was not encountered and could be because the lungs were ventilated before the procedure with 100% oxygen and the actual duration of negative suctioning was limited to a very short period and ventilation of the right lung resumed at the earliest opportunity. The chances of bronchial blocker balloon displacement when

positioning the child in the right lateral decubitus position after achieving the lung separation in the supine position can be minimized if the head and the torso can be turned in unison without undue flexion or extension of the neck. The authors did not encounter any balloon displacement during positioning. The authors have found that left bronchial intubation using the third technique is of great use in the intensive care setting in which isolated left bronchial suctioning and re-expansion of the collapsed left lung had to be done.

In conclusion, the technique of left bronchial intubation with an SLET, with the bevel facing right and that is preshaped to resemble a left-sided double-lumen tube, was simple, safe, and easily accomplished. A Fogarty catheter, with the markings made on it, can be positioned properly without the aid of a smaller bronchoscope once the left bronchus is intubated. Balloon displacement can be avoided completely if the left lung is collapsed properly and completely before the final balloon inflation.

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